

REMARKS

In the present Amendment, claim 1 has been amended to incorporate the subject matter of claim 2 and to recite an isolated lactic acid bacterial strain belonging to the genus *Lactococcus*. Claim 2 has been cancelled. Claims 3 and 4 have been amended in view of the amendment to claim 1. Claims 9, 11 and 13 have been amended similarly. Claim 10 has been cancelled. New claim 14 has been added. Support for claim 14 is found, for example, at page 16, lines 5-9 and page 23, lines 20-24 of the specification. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1, 3-9 and 11-14 will be pending, of which claims 9, 11 and 12 are withdrawn from consideration.

At page 2 of the Action, claims 1 and 4-8 are rejected under 35 U.S.C. § 102(e) as being anticipated by Setchell *et al.* (US 7,396,855, "Setchell").

At page 3 of the Action, claims 1-8 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Setchell in view of Elliott *et al.* (Journal of Clinical Microbiology, 1991, 29(12): 2731-2734, "Elliott").

Applicants submit that the above two rejections should be withdrawn because Setchell and Elliott do not disclose or render obvious the present invention, either alone or in combination.

In the Amendment filed December 4, 2009, Applicants explained that Setchell nowhere discloses that daidzein can be converted into equol using only one of the six strains.

In response, the Examiner states that the invention is claimed broadly as a composition that comprises “as an essential component” an undefined amount of an unidentified strain of *Lactococcus* that “has an ability to utilize” at least one of various compounds “to produce equol.”

The Examiner notes that the amount of daidzein, the amount of *Lactococcus* and the amount of equol contained in the composition are not claimed and that Applicants have not shown with objective evidence that one of the strains of Setchell is incapable of utilizing at least one of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol.

However, Setchell teaches employing a mixed culture of the six strains to convert daidzein into equol (col. 12, lines 18-21 and Example 5) and does not teach only one of the six strains can be used to convert daidzein into equol.

Further, Applicants explained, in the Amendment filed December 4, 2009, that the production of equol from daidzein follows the synthetic route of daidzein → dihydrodaidzein → tetrahydrodaidzein → equol. Therefore, in order to produce equol using a single strain, the strain must have all the enzymes needed for these conversions. However, Setchell merely teaches that the conversion of daidzein to equol was observed when a mixed culture containing the six strains was used. In other words, Setchell is silent about the production of equol using a single strain that can carry out all of the conversions of daidzein → dihydrodaidzein → tetrahydrodaidzein → equol. In contrast, the instant claims recite a novel strain of lactic acid bacterium which can be used *alone* to utilize daidzein compounds in soy milk to make equol. In this respect, the specification discloses that no lactic acid bacteria of the genus *Lactococcus* are known that have

an equol producing ability (i.e., that can make equol from daidzein compounds in soy milk). *See* Specification, page 10, lines 12-16.

The Examiner has not provided any evidence, and it is the Examiner's burden, to show that one of the strains of Setchell is necessarily capable of utilizing at least one of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol. Applicants respectfully request the Examiner to fulfill his burden.

Further, claim 1 as amended recites an isolated (isolated from nature) lactic acid bacterial strain, and that the bacterial strain is *Lactococcus garvieae*.

Setchell does not teach or suggest *Lactococcus garvieae*, much less the single strain *Lactococcus garvieae* having an ability to convert daidzein into equol.

Regarding the lack of disclosure in Setchell of *L. garvieae* FERM BP-10036, the Examiner states that the depository identification is not an inherent property of a given strain and that strains are often re-deposited and identical strains may have several deposit accession numbers from the same or different depositories.

Again, the Examiner has not provided any evidence to support his assertion. The Examiner should have searched and found the correct number if his assertion is true. Accordingly, Applicants respectfully request the Examiner to provide evidence to support his assertion.

In view of the above, reconsideration and withdrawal of the §§102/103 rejections based on Setchell and Elliott are respectfully requested.

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/562,687

Attorney Docket No.: Q92435

New claim 14 is patentable over the cited references for at least the same reasons that claims 1, 3-8 and 13 are patentable over the cited references, as discussed above.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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CUSTOMER NUMBER

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